

II. Response to Detailed Action

A. Election/Restrictions

Claims 1-20 have been cancelled and replaced by new claims 21-34.

Applicants have elected to pursue in this application the processes for using superparamagnetic particles formerly covered by now cancelled claims 3-18.

B. Response to Claim Rejection Under 35 U.S.C. 112

By this amendment, the limitations of product claims 1 and 2 relating to superparamagnetic particles have been incorporated in new process claims, rewritten to cover the use of the superparamagnetic particles covered by now cancelled claims 1,2, 19 and 20 in the process of

(a) sequestering an identified biological ligand from a dilute aqueous solution thereof by first coating superparamagnetic particles of the defined type with a natural binding partner for the ligand whereby particle-binding partner complexes are formed, immersing the coated particles in the dilute solution and allowing reaction to occur between the ligand and its binding partner during an incubation period thereby forming particle-binding partner-ligand complexes, subjecting these complexes to the action of a strong magnetic field which causes them to acquire magnetic charge and be drawn closer to one another, and then removing the liquid, washing the particles and resuspending them in a small volume of fresh aqueous buffer and then

(b) applying the magnetized particles in suspension in buffer to one end of an immunochromatographic ("ICT") strip, to the other end of which has been *immovably affixed* one or more discrete stripes of a binding partner for the ligand and allowing the coated particles to migrate along the strip and contact the immovable stripe(s) of binding partner for the ligand and react therewith, forming tagged binding partner-ligand-immovable binding partner complex "sandwiches" (in which the binding partners may be the same substance or two different ones, as covered in the dependent claims). The magnetized particles which bind to the immobilized stripe(s) of biological binding partner are then subjected to measurement of

their combined magnetic charge strength in order to determine the amount of biological ligand removed from the dilute solution, using a standard curve wherein measured magnetic charge intensity has been plotted against known amounts of target ligand contained in standardized samples that were tested in the claimed process

A conscientious effort has been made to cure the vagueness referred to in the action by eliminating the expression “in the known manner” and making clear that the first binding partner initially coated on the particles and the second binding partner immovably striped on the ICT strip may be different binding partners-i.e. different substances--or may be the same binding partner. An effort has also been made to make clear that the magnetization of the particles coated with ligand-first binding partner reaction product, not only aids in separating them from the large volume of the original sample but also imparts a magnetic charge to the superparamagnetic particles which persists through the short ICT process, enabling the magnetic charge intensity of those particles that bind to the immobilized binding partner striped on the ICT strip to be measured and correlated through a preconstructed standard curve to the amount of ligand originally present in the dilute aqueous sample.

C. Response to Prior Art Rejections

The new claims 21-34 all include the combination of (a) the use of the supermagnetic particles coated with binding partner for the biological ligand to concentrate and separate the ligand from a dilute solution and (b) the next phase in which these particles, having been subjected to the magnetizing influence of a strong magnetic field to aid in separating them from the solution, now act as tags for “sandwiches” of ligand molecule contained between two binding partner molecules, whereby the measurement of their total magnetic charge strength is correlatable to the amount of ligand present as read from a previously constructed standard curve made with standardized samples containing known amounts of ligand. The curve is obtained conventionally for each biological ligand of interest, by seeding successive aliquots of a standard aqueous solution with different known amounts of biological ligand, running the entire process identically on each aliquot, and plotting the known ligand concentration against total measured magnetic charge for each aliquot run.

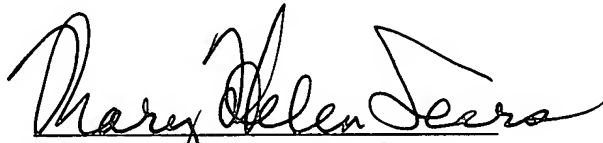
As the action recognizes, none of Miltenyi et al, Rembaum et al or Liberti et al--the three references applied to the previous, now-cancelled claims under 35 USC §§102 and 103--employs *the same* superparamagnetic particles to concentrate ligand from a dilute solution and to act as a tag enabling their quantification.

US Patent 6,607,922 and its PgPub document disclose using superparamagnetic particles as tags, but the particles are embedded in a test strip and reacted with ligands in samples only upon application of sample to the strip. These documents do not suggest a procedure in any way akin to that covered by claims 21-34.

III. Conclusions

It is believed that the present claims are in condition for allowance and action to that effect is accordingly courteously requested. If, however, the Examiner should be of the view that informalities are still present, which could be handled by a telephone discussion, Applicants' attorney hereby invites such a call to her at the number shown below.

Respectfully submitted,

A handwritten signature in black ink, reading "Mary Helen Sears". The signature is fluid and cursive, with the first name "Mary" and last name "Sears" being more prominent than the middle name "Helen".

Mary Helen Sears, Reg. 19,961

Attorney for Applicants

The M.H. Sears Law Firm, Chartered

910 Seventeenth Street, N.W., Suite #800

Washington, D.C. 20006

Telephone: (202) 463-3892

Telecopy: (202) 463-4852